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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,158	12/16/1999	ERLING SUNDREHAGEN	697.011US1	7192

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/464,158	SUNDREHAGEN	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed October 2, 2001 has been entered. The specification and claims 1-5 have been amended. Claims 1-12 are under consideration in this office action.

Response to Arguments

2. Applicant's arguments filed October 2, 2001 have been fully considered but they are not persuasive.

Claim Objections

3. The objection of claims 3-12 under 37 CFR 1.75© as being in improper form because the dependant claims are dependant upon other multiple dependent claims is maintained. Applicant asserts that a preliminary amendment was filed December 16, 1999 however there is no record of such amendment. Applicant is asked to send a copy of the amendment with the next reply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 3 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons already of record.

The rejection was on the grounds that claims 3 and 5 are vague and indefinite for their recitation of "fragments thereof" and "mixtures thereof". Applicant asserts that the

claims are not indefinite because the specification teaches that combinations of different carbohydrate ligands are disclosed to have increased capacity and hence provide better separation of transferring isoforms.

However, it is the examiner's position that the specification does not teach how to make mixtures of the ligands. There is no teaching of what portions of each ligand to use in the mixture. There is no precise definition of mixtures thereof. There is no teaching of what antibody fragments thereof are to be used in the method. The passages to which applicant refers do not teach fragments thereof or mixtures thereof. The passages merely recite a variety of ligands that are capable of binding. Therefore it is unclear how to define the metes and bounds of these terms. Clarification is required to overcome this rejection.

5. The rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained. Applicant argues that it is not clear why a contact step is necessary. However, it is examiner's position that all method steps must be positively recited in the claims. *Ex parte Erlich* 3 USPQ 101. Without the recitation of a contact step and detection step, one cannot be reasonably apprised of the method steps in this method claim. The specification teaches the use of many methods requiring a contact step and a detection step, thus the claims must positively recite these same steps. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 1-3, 6-8 and 10-12 under 35 U.S.C. 102(b) as being anticipated by Sundrehagen (WO 91/19983) is maintained for reasons of record. The rejection was on the grounds that Sundrehagen teaches assessing the concentration of a subset of analyte variants within a group of different analyte variants, test kits and reagents composition for use in such method. The assessment of the level of different transferrin in serum is of particular importance because transferrin in chronic alcohol abusers has a desialylated transferring isoform. This transferrin carries two or less sialyl residues, is relatively increased in content when compared to non-alcoholics and is called Desialylated transferrin or Carbohydrate Deficient Transferrin (CDT).

Applicant urges that Sundrehagen does not teach or suggest carbohydrate free transferring (CFT) and that CDT contains some carbohydrate containing transferrin moieties. However, it is the examiner's position that the CDT of Sundrehagen teaches the invention as described by the instant application. The specification at page 7 beginning at line 14 defines CFT as a transferrin which does not carry at least 60% or more carbohydrate chains, thus the CDT of Sundrehagen meets the limitations of the claims. Furthermore, applicant has not shown any structural differences between the transferrin isoforms. Applicants have not shown the substantial absence of carbohydrate by the lack of any detectable binding lectins or other carbohydrate binding proteins to CDT. Applicant merely states the conclusion that CDT does not meet the

limitations of the claims without providing any scientific evidence. Thus the argument is not persuasive and the claims remain rejected.

Applicant also argues that Sundrehagen teaches fractionation for separation and that the instant application does not require this same method. However, it is the examiner's position that the instant claims do not restrict the separation techniques used. The claims simply recite separation, thus the method of Sundrehagen is encompassed within the methods of the instant application. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The rejection of claims 4-5 under 35 U.S.C. 103(a) as being unpatentable over Sundrehagen (WO 91/19983) in view of Pekelharing et al., (Analytical Biochem) is maintained for reasons already of record. Sundrehagen (WO 91/19983) has been discussed above. However, the rejection was on the grounds that it would have been obvious at the time of applicants invention to use a modified ELISA by replacing the immobilized antibody or enzyme linked antibody with a lectin or other carbohydrate binding protein of Pekelharing et al., (Analytical Biochem) in the method of assessment of alcohol consumption as taught by Sundrehagen, because Pekelharing et al., teach that the use of lectins increases the speed, specificity, sensitivity and simplicity of an immunoassay.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have been motivated to make such a change such as a alternative and functionally equivalent modified ELISA since only the expected results would have been obtained. The prior art clearly teaches replacing the immobilized antibody or enzyme linked antibody with a lectin or other carbohydrate binding protein to create a heterologous lectin-enzyme immunoassay system, therefore, a skilled artisan would have had a reasonable expectation of success in switching the lectin. The use of an alternative technique would have been desirable to those of ordinary skill in the art based on the fact that the modified immunoassay has increased sensitivity when subfractions are to quantitated; increases the captured protein; increases binding affinity; and increases speed, specificity and simplicity when microtiter plates are used.

Applicant urges that Pekelharing et al., do not teach CFT isoforms, therefore Pekelharing et al., do not teach or suggest the instant invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Sundrehagen (WO 91/19983) in view of Dreher et al., Canadian Patent 2,074,345.

In response to applicant's general argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Sundrehagen (WO 91/19983) has been discussed above. It is the examiner's position that no more then routine skill would have been required to use well known methods for transferrin determination using immunoturbidimetry and immunonephelometry techniques as taught by Dreher et al., in the method of assessment of transferrin as taught by Sundrehagen, because Dreher et al., teach that immunoturbidimetry and immunonephelometry techniques can be easily and simply automated. Thus, the rejection is maintained.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

MARK NAVARRO
PRIMARY EXAMINER

December 16, 2001